Rejections of the Claims Under §103

Claims 1-5, 9, 12-13, 21-22, and 26-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Slettenmark et al. (U.S. 5,344,432) in view of Hammon III et al. (U.S. Patent No. 6,037,715) in view of De Lucia (U.S. Patent No. 3,604,870).

Claims 6-8, 23-25 and 28-29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Slettenmark et al. (U.S. 5,344,432) in view of Hammon III et al. (U.S. Patent No. 6,037,715) in view of De Lucia (U.S. Patent No. 3,604,870) and further in view of Jabagchourian et al. (U.S. Patent No. 4,506,244).

Claims 10-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Slettenmark et al. (U.S. 5,344,432) in view of Hammon III et al. (U.S. Patent No. 6,037,715) in view of De Lucia (U.S. Patent No. 3,604,870) and further in view of Lingal et al. (U.S. Patent No. 2,757,261).

Claims 14-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Slettenmark et al. (U.S. 5,344,432) in view of Hammon III et al. (U.S. Patent No. 6,037,715) in view of De Lucia (U.S. Patent No. 3,604,870) and further in view of Glauser et al. (U.S. Patent No. 6,894,246).

In addressing the above rejections, each of Applicants' independent claims 1, 12 and 26 are rejected on the first-listed basis, as being obvious over Slettenmark et al. in view of Hammon III and De Lucia. Each of the additional rejections of dependent claims is premised on this combination of references. Because Applicants will show that the above references fail to establish a *prima facie* case of unpatentability of these independent claims, Applicants' remarks will focus on the rejections of those independent claims.

Independent claims 1, 12 and 26 are as follows:

1. An implantable device comprising:
a sealed housing;

a plurality of electrical components disposed within the housing and including at least one pair of adjacent electrically conductive paths wherein the paths are separated by a distance less than approximately 0.01 inches; and

a gas mixture of at least 1 percent sulfur hexafluoride disposed within the housing.

12. A method comprising:

assembling a plurality of electrical components in an implantable housing wherein the plurality includes a pair of conductive paths separated by a distance of less than approximately 0.01 inches;

introducing a gaseous mixture of at least 1 percent sulfur hexafluoride to an interior of the housing; and

sealing the housing to prevent release of the gas mixture.

26. An implantable device comprising:

a sealed housing;

a plurality of electrical components disposed within the housing and including at least one pair of adjacent electrically conductive paths wherein the paths are separated by a distance less than approximately 0.01 inches; and

a gas mixture having a dielectric constant greater than unity disposed within the housing.

Applicants' apparatus claims 1 and 26 are each drawn to an "implantable device," and method claim 12 recites a method including assembling "electrical components in an implantable housing." Thus, all pending claims expressly address an implantable device. Additionally, each claim recites a pair of conductive paths in the implantable device wherein the paths are separated by a distance less than approximately one-hundredth of an inch.

The law is well-established that to establish a *prima facie* case of obviousness over a combination of references, there must be some reason, suggestion or motivation found in the prior art, by which a person of ordinary skill in the art would make that combination.[1] Where the combination comes about only from hindsight reconstruction based on the Applicant's disclosure, that combination is insufficient to establish a *prima facie* case of obviousness.[2] Further, each reference must be "analogous prior art" to the claimed invention under examination. The MPEP instructs that to be analogous prior art, a reference must either be in the

[1] *See* e.g., *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).
[2] See Id.

field of Applicant's endeavor, or if not, must then be reasonably pertinent to the particular problem with which the inventor was concerned.[3]

In the rejection presented in the Office Action, the primary reference to Slettenmark clearly addresses a similar problem to that facing Applicants-- improving the dielectric environment within an implantable medical device to provide greater electrical insulation for circuitry within the device. The other references in the rejection, however, are outside the field of Applicants' endeavor, and are not pertinent to implantable devices. Whatever the prior art technologies that were known for improving dielectric performance, each was of no real value to one seeking to construct electrical circuitry or improve dielectric performance in an implantable device unless there was some indication of compatibility of the technology with a device constructed for implantation. Neither of the additional references in the rejection indicates such compatibility.

A. The Hammon Reference

The Office Action relies upon Hammon to teach that "it is known to use a plurality of electrical components disposed within the housing and including at least one pair of adjacent electrically conductive paths wherein the paths are separated by a distance less than approximately 0.01 inches...." Specifically, the Office Action cites a passage of Hammon that describes a spark gap in the disclosed relay of between 0.001 inch and 1 inch, and preferably 0.25 inch diameter.[4]

Hammon, however, does not relate to any form of implantable medical device. In stark contrast, Hammon describes a high voltage electric switch intended to be used in power systems in excess of 1kV.[5] Hammon's disclosed high-voltage, high-current spark gap switch, with its eroding electrode and ejected debris is clearly inconsistent with any aspect of an implantable device[6]:

> Spark gap switches are often the most rugged switches available for high-peak-power systems. However, they are generally limited to less than 500,000 Coulombs of operational life, where one (1) coulomb is the charge transferred by

[3] MPEP § 2141.01(a) (quoting *In re Oetiker*).
[4] Hammon, Column 4, line 31.
[5] Hammon, Column 1, lines 8-10.
[6] Hammon, Column 2, line 53 to Column 3, line 8.

the flow of a current of one (1) Ampere for one (1) second.

The operation of a spark gap switch produces spark breakdown current between the electrodes. Spark breakdown current is current flow between electrodes, which produces a hot plasma having gaseous, molten and solid debris as a byproduct. Spark breakdown current is detrimental to the surface of the electrodes and causes them to become pitted and eroded. Debris from the spark breakdown current also degrades any surrounding materials such as insulating materials used to hold the electrodes in place.

The present invention discloses a new and improved spark switch design that inserts an inner electrode into an outer electrode, thereby increasing the amount of material that can be eroded before changing the gap length, and thereby increasing the operational life of a switch. The design also enables the outer electrode to serve as a containment vessel thereby restricting the trajectory of debris caused by the breakdown current.

Thus, Hammon discloses a high voltage switch which will repeatedly arc across a defined electrode gap, eroding the electrodes and ejecting solid, molten and gaseous debris in the process. Such a device is clearly far removed both from the implantable medical device of Slettenmark and from the problems which faced the Applicants. The mere fact that Hammon discloses a spark gap in its high voltage switch, in an environment that includes sulfur hexafluoride, does not imply that one trying to improve the dielectric performance in an implantable device would look to such a radically different field of endeavor for guidance. Thus, Applicants respectfully submit that Hammon does not represent analogous art which may be properly combined in a rejection of Applicants' claims under § 103.

Further, Applicants submit that even if Hammon is considered, it cannot be properly relied on for the teaching identified on the Office Action. The Office Action states that:

> ...it would have been obvious...to modify the device and method as taught by Slettenmark with a plurality of electrical components disposed within the housing and including at least one pair of adjacent electrically conductive paths wherein the paths are separated by a distance less than approximately 0.01 inches, as taught by Hammon et al. since such a modification would provide an implantable medical device with a smaller relay gap for the path of adjacent electrically conductive path [sic], that it is known to use conductive paths that are separated by a distance of less than 0.004 inches [sic: 0.001 inch] as set forth in [Column 4, line 31] to provide a smaller relay gap and as a result a smaller device.

Applicants respectfully submit that even if Hammon is considered, no such teaching exists to modify the device of Slettenmark. The structure of Hammon is so far removed from the

device of Slettenmark that there is no reasonable suggestion of the described combination. The mere fact that Hammon discloses a spark gap as small as 0.001 inch in the high-voltage switch provides no motivation whatsoever to modify the implantable device of Slettenmark to provide such a dimension between conductors. It is virtually inconceivable that one seeking to determine a spacing between conductors appropriate for use in an implantable medical device would look for guidance to a description of a high voltage spark gap switch used for power switching applications. Any such motivation could only come from hindsight reconstruction based on Applicants' disclosure. And such use of hindsight is, of course, clearly impermissible.[7]

B. The De Lucia Reference

The Office Action relies upon De Lucia to teach that it was known to use "a gas mixture of at least 1 percent sulfur hexafluoride disposed within the housing."[8] However, the only "housing" that De Lucia discloses is a glass envelope for a magnetically-operated high voltage relay, suitable for use in multiple situations, including in an external defibrillator system.[9] The defibrillator is not expressly identified as an external -- non-implantable--defibrillator. However, De Lucia's depiction and description of the preferred embodiment make this very clear. For example the described relay includes a glass envelope 10, which is surrounded by a molded rubberized casing 60, which is there to protect the relay unit to prevent its breakage, and the resulting "explosion and escape of the pressurized gas within the envelope."[10] Additionally, the specification is clear that the relay is selectively connected to a patient, when the described relay is used for heart defibrillation purposes.[11] The disclosed structure is thus clearly not an implantable device.

Applicants submit that although De Lucia discloses a device used as a defibrillator, the fact that it is not an implantable device makes the reference of minimal value to those facing the problems of improving dielectric performance in an implantable device, as were Applicants. Just the identified risk of explosion is sufficient to emphasize the irrelevance of De Lucia's disclosed device to one trying to solve the problems of building an improved implantable device.

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[7] *See* e.g., *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).
[8] Citing to De Lucia, Column 2, line 64.
[9] De Lucia, Column 1, lines 9-15.
[10] De Lucia, Column 4, lines 61-69.
[11] De Lucia, Column 5, lines 3-6.

Applicants submit, therefore, that De Lucia is not analogous prior art under the guidance of the Federal Circuit and MPEP. Accordingly, the reference is therefore not properly relied upon in the rejection.

For all the stated reasons, Applicants respectfully submit that the Hammon and De Lucia references are simply not analogous prior art that may properly be relied upon to establish a prima facie case of obviousness of any of independent claims 1, 12 and 26. Further, even if Hammon is relied upon, it simply does not in any way suggest the combination with Slettenmark to approach Applicants' invention as recited in those claims. Accordingly, the Office Action fails to establish a *prima facie* case of unpatentability of Applicants' independent claims. Because all other claims in the application depend, directly or indirectly, from one of the independent claims, Applicants believe that each of claims 2-11, 13-25 and 27-29 has been shown to also be allowable, at least as depending from an allowable independent claim.

CONCLUSION

Applicants respectfully submit that all claims are in condition for allowance, and notification to that effect is earnestly requested. If there are any matters that may be resolved or clarified through telephone interview, the Examiner is respectfully requested to telephone Applicant's attorney at (512) 628-9324.

If necessary, please charge any additional fees or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date April 24, 2007

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 24th day of April 2007.

Name

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